APPENDIX F

WORKPLAN AND CHECKLIST FOR PRA

F.0 INTRODUCTION

This appendix provides guidance on developing a workplan prior to the initiation of a probabilistic risk assessment (PRA), and using a checklist when reviewing a PRA. Like the quality assurance project plan (QAPP), the workplan for PRA generally should document the combined decisions or positions of the remedial project manager (RPM), risk assessor, and stakeholders involved in the risk assessment. Often there are many stakeholders in a risk assessment, and it is important to involve and engage all stakeholders early in the decision-making process. These are important steps that should save time and effort.

EXHIBIT F-1

EXAMPLES OF ELEMENTS OF THE WORKPLAN FOR PRA

1. Statement of the ecological assessment endpoints and/or human risk
2. Summary of the point estimate risk assessment
3. Potential value added for risk management by conducting a PRA and proceeding to the subsequent tiers (quantify variability, uncertainty, or both)
4. Discussion of adequacy of environmental sampling for PRA (e.g., data quality issues)
5. Description of the methods and models to be used (e.g., model and parameter selection criteria)
6. Proposal and basis for probability distributions and point estimates
7. Methods for deriving the concentration term
8. Proposal for probabilistic sensitivity analysis
9. Method for dealing with correlations
10. Bibliography of relevant literature
11. Software (i.e., date and version of product, random number generator)
12. Simulation approach (e.g., iterations, Monte Carlo or Latin Hypercube sampling, time step)

F.1.0 WORKPLAN

In general, PRAs may be developed by Environmental Protection Agency (EPA), EPA contractors, or a potentially responsible party (PRP) with appropriate EPA oversight. In each case, it is important to develop a workplan early in the risk assessment process. PRAs to be submitted by a contractor or PRP should generally be submitted for EPA review before commencing the analysis. The workplan should describe the software to be used, the exposure routes and models, and input probability distributions and their basis (e.g., relevance to the site-specific contamination and pathways), including appropriate literature references. Examples of the elements of a workplan are given in Exhibit F-1, as well as Exhibit 4-8 in Chapter 4 (Example Elements of a Workplan for Ecological PRA). It is important that the risk assessor and risk manager discuss the scope of the probabilistic analysis and the potential impact on the Remedial Investigation/Feasibility Study (RI/FS).

☞ *Given the time and effort that can be expected to be invested in conducting a PRA, it is important that a workplan undergo review and approval by EPA, prior to proceeding with the assessment.*

The EPA generally will not accept probabilistic analysis where a workplan for the analysis has not been initially submitted to the Agency and approved by the Regional risk assessor and RPM. Exceptions to this process may be considered on a case-by-case basis.

Conducting a PRA is an iterative process. In general, as new information becomes available, it should be used to evaluate the need to move to a higher tier. The decision to move an assessment to a higher tier of complexity should result in a revised workplan and consultation with the Agency. The previous PRA, and its sensitivity analysis, should be included in the revised workplan, along with a point estimate risk assessment based on any data collected as part of a lower tier. The assessment will often be restricted to the chemicals and pathways of concern that contribute the greatest risk.

Throughout the process of developing the PRA, the EPA risk assessor and the personnel involved in developing the assessment should have a continuing dialogue to discuss the many Agency decisions and their potential impact on the assessment. This dialogue, along with interim deliverables, will help to ensure that the risk assessment report will meet the needs of the Agency and that any problems are identified and corrected early in the process.

F.2.0 FOCAL POINTS FOR PRA REVIEW

In reviewing a PRA, it is recommended that a systematic approach be adopted to ensure that all key technical elements of the PRA are evaluated and potential weaknesses are identified. A review check list can facilitate this process and promote consistency in the reviews of PRAs. Such a list can be developed from EPA's guiding principles (U.S. EPA, 1997) and other reviews on the subject of PRA quality review (e.g., Burmaster and Anderson, 1994).

In general, the review of a PRA can be organized into four focal points listed in Exhibit F-2. PRAs can vary in complexity, from relatively simple to very complicated; thus, the review strategy may need to be customized for specific sites.

EXHIBIT F-2

KEY FOCAL POINTS FOR PRA REVIEW

1. Clarity of and conformation to objectives.
2. Scientific basis and documentation of input distributions and assumptions.
3. Model structure and computational mechanics.
4. Results, including, limitations, reasonableness, and clarity of documentation.

F.3.0 CHECKLIST FOR REVIEWERS

The exposure pathways and chemicals considered in a PRA should be clearly stated and related to the assessment endpoint. Often, the simplest way of doing this is to use the site conceptual model.

Table F-1 provides a list of major points that may be used to evaluate the quality of a probabilistic assessment. This is not an exhaustive list. The ultimate judgment of the acceptability of a PRA is the responsibility of the regional EPA personnel.

The issues that a reviewer should focus on may be different for each assessment. The workplan and the assessment should address each of the items on the checklist, but the workplan may include

additional items. The reviewer is responsible for ensuring that the workplan and the assessment are complete and of sufficient quality to help support a risk management decision under the National Contingency Plan (NCP).

The report should include a discussion of the results of assessment and how they relate to the point estimate of risk and hazard. A clear and concise description of what the results mean is an important part of each report.

F.4.0 INTERNAL AND EXTERNAL REVIEW

There are two levels of review that may be appropriate for a PRA. If an EPA reviewer feels the need for help with a review, other EPA personnel may be contacted formally or informally to provide additional review capabilities. The EPA personnel should also review the draft workplan for PRA to evaluate the appropriateness and consistency with Agency guidance. If EPA personnel are contacted early in the risk assessment process, the review can occur in a more productive and timely manner.

When the issues at a particular site are complex or contentious, EPA reviewers may also wish to obtain the services of outside experts for peer review (U.S. EPA, 2000). According to EPA's Peer-Review Policy Statement dated June 7, 1994 (U.S. EPA, 1994), "Major scientifically and technically based work products related to Agency decisions normally should be peer-reviewed." External peer review should be considered when allocating resources for a PRA. The EPA reviewers generally should select external peer reviewers who possess no bias or agenda regarding the process or methods of PRA.

Table F-1. Example of a Generic Checklist for Reviewers [2 pages]

Focal Point	✔	Evaluation Criterion
Objectives and Purpose		
Assessment Endpoints	✔	Are the human health and/or ecological assessment endpoints clearly stated and consistent with the workplan?
Benefits	✔	Are the rationales for, and benefits of, performing the PRA clearly stated and consistent with the workplan?
Site Conceptual Model	✔	Is there a description or graphic representation of the receptors and pathways considered in the assessment? Has the PRA addressed each of the pathways for completeness (e.g., sources, release mechanisms, transport media, route of entry, receptor)?
Separation of Variability and Uncertainty	✔	What is the modeling strategy for separating variability and uncertainty in the PRA? Is this strategy consistent with the assessment endpoints?
Model Structure and Computational Mechanics		
Flow Chart	✔	Is a diagram of the computational sequence provided so that the pathways of inputs and outputs and data capture can be understood and easily communicated?
1-D MCA / 2-D MCA	✔	Is a 1-D MCA or 2-D MCA being implemented in the PRA? What is represented by either or both dimensions?
Algorithms	✔	Are all algorithms used in the model documented in adequate detail to recreate the analysis?
Integration	✔	Are the algorithms used in numerical integration identified and documented?
Dimensional Analysis	✔	Has a unit analysis been conducted to ensure that all equations balance dimensionally?
Random Number Generation	✔	What random number generator is used in model computations? Is it robust enough? What reseeding approach is used to minimize repeated sequences?
Input Distributions and Assumptions		
Variability and Uncertainty	✔	Is there a clear distinction and segregation of distributions intended to represent variability from distributions intended to represent uncertainty?
Data sources	✔	Are the data or analysis sources used in developing or selecting the input distributions documented and appropriate for the site?
Distribution Forms	✔	Are the analyses used in selecting the form of the distribution adequately documented (i.e., understandable and repeatable by a third party?)
Distribution Parameters	✔	Are the analyses used to estimate the distribution parameters adequately documented?
Distribution Tails	✔	Do the estimation methods precisely depict the tails of the input distributions; how was this evaluated? Is there sufficient information to depict tails for empirical distributions? Are these estimated as exponential tails with bounding values?
Truncations	✔	Are any input distributions truncated? Do these truncations make sense? Should truncations be applied to any of the distributions?
Concentration Term	✔	Is the derivation of a point estimate or distribution for the concentration term adequately documented? Is sufficient information provided to enable the reviewer to recreate the concentration term?
Variable Correlations	✔	Have variable independence and correlations been addressed? Has the methodology for representing variable correlations in the model been documented and is it reasonable in terms of the variables, the site, and the statistical approach?

Focal Point	✔	Evaluation Criterion
Time Step	✔	Has the basis for the time step used in the model been documented? Is a single time step used, or do variables have different time steps? Are the time steps conceptually reasonable for the variables; for the site? Has the time step been evaluated in the sensitivity analysis?
Sensitivity Analysis	✔	Has a sensitivity analysis been conducted? Are the methods used in the analysis statistically valid? What did the analysis reveal about uncertainties in the assessment and the relative contributions of input variables to uncertainty?
Results of Modeling		
Completeness	✔	Are all the exposure routes identified in the site conceptual model and workplan addressed in the model results? Has the PRA fulfilled the objectives and satisfied the purpose stated in the workplan?
Point Estimate Calculation	✔	Has a point estimate calculation, using mean or median values of the input distributions, been performed? How do these results compare with the central tendencies calculated with the probabilistic model? How do the reasonable maximum exposure (RME) estimates compare? Have the similarities or differences between risk estimates from the point estimate and probabilistic approaches been adequately addressed?
Stability of Output Tails	✔	Has the stability of the high-end tail of the risk distribution been adequately evaluated? How stable are the estimated tails (in quantitative terms?) Is this level of stability adequate to support the risk management decisions that the model is intended to support?
Significant Figures	✔	Is the number of significant figures used in the output reasonable and consistent with model uncertainty?
Limitations	✔	Are the strengths and weaknesses of the PRA methodology and limitations of the results for decision making clearly presented?
Clarity	✔	Are the results and conclusions clearly presented and consistent with model output (e.g., central tendency exposure (CTE) and RME identified in the Executive Summary along with discussion of uncertainty)?
Graphics	✔	Are there graphics included that show both the risk distribution and PRA results (e.g., CTE and RME risk)?

REFERENCES FOR APPENDIX F

Burmaster, D.E. and P.D. Anderson. 1994. Principles of Good Practice for the Use of Monte Carlo Techniques in Human Health and Ecological Risk Assessment. *Risk Anal.* 14(4):477–481.

U.S. EPA. 1994. Memorandum from Deputy Administrator Carol Browner on *Peer Review and Peer Involvement at the U.S. Environmental Protection Agency*. June 7.

U.S. EPA. 1997. Memorandum from Deputy Administrator Fred Hansen on the *Use of Probabilistic Techniques (including Monte Carlo Analysis) in Risk Assessment*, and *Guiding Principles for Monte Carlo Analysis*. Office of Research and Development, Washington, DC. EPA/630/R–97/001. May 15.

U.S. EPA. 2000. *Peer Review Handbook: 2nd Edition.* Science Policy Council. Washington, DC. EPA/100/B-00/001. December.